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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311 (US).

(72) Inventors: SMITH, Scott, R.; 6950 County Road 10, Chaska, MN 55318 (US). KILLION, Douglas, P.; 6252 Dallas Court, Maple Grove, MN 55311 (US).

(74) Agent: GRAD, Jonathan; Vidas, Arrett & Steinkraus, 6109 Blue Circle Drive, Suite 2000, Minnetonka, MN 55343-9185 (US).

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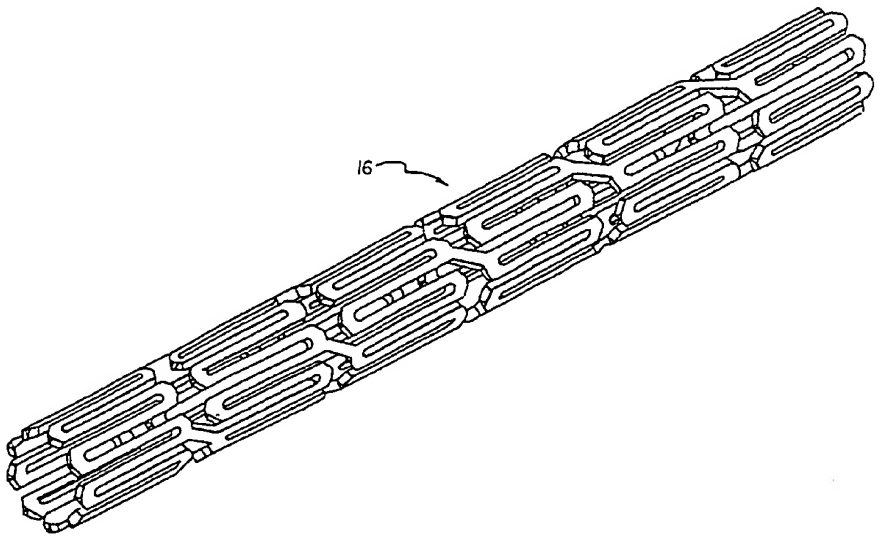
(54) Title: FLEXIBLE SEGMENTED STENTS



(57) Abstract: A radially expandable segmented stent having plastic, i.e., permanent deformation, connectors interconnecting each segment.

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FLEXIBLE SEGMENTED STENTS

BACKGROUND OF THE INVENTION

This invention relates to multiple interconnected stents or stent segments, the interconnections being comprised of lengths of a plastic material. The term "plastic" is used herein to refer to materials which are capable of being deformed permanently without rupture.

In the prior art, stents are well known for use in opening and reinforcing the interior wall of blood vessels and other body conduits.

Stents are generally tubular, radially expandable and may be of the self-expanding type or may be expandable with an outward pressure applied to the stent, typically by expansion of an interiorly positioned balloon. Stents are made of various materials such as plastic or metal, metal usually being preferred.

Since stents must be of somewhat rigid design to provide reinforcement support and may be required to be of considerable length in order to extend over a lengthy area, it is difficult to resolve this need for rigidity with the need of having a flexible stent which is readily implanted by inserting it through a sometimes tortuous curving path as is often encountered in the percutaneous insertion technique typically used for implantation of stents. This is further complicated by the fact that stents must be readily expandable upon implantation to provide a support structure.

It is known that a plurality of stent elements can be loosely interconnected together by filaments or the like to provide a lengthy flexible stent arrangement. Such arrangements are shown in the following patents for example:

U.S. Patent No. 5,405,377 to Cragg

U.S. Patent No. 5,665,115 to Cragg

U.S. Patent No. 5,755,781 to Jayaraman

U.S. Patent No. 5,443,476 to Schwartz et al.

U.S. Patent No. 5,135,536 to Hillstead

U.S. Patent No. 5,035,706 to Gianturco et al.

WO 93/13825 (PCT) to Maeda et al.

The following technical literature is also of interest in this regard:

Tracheobronchial Tree: Expandable Metallic Stents Used in Experimental and Clinical Applications, Work in Progress; Radiology, Feb. 1986, pp 309-312.

Experimental intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents; Radiology, Feb. 1987, 162: 481-485.

Gianturco Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrome Recurring After Maximum - Tolerance Radiation; Cancer, Sept. 1987, Vol. 60, pp 1243 - 1246.

Modified Gianturco Expandable Wire Stents in Experimental And Clinical Use; Cerise, *Porto Cervo,* May 1987, pp 100-103.

BRIEF SUMMARY OF THE INVENTION

This invention is directed to an improvement in the general concept of joined stents or stent segments (hereinafter referred to collectively as "stent segments") in which a "plastic" material (capable of exhibiting permanent deformation) extends between stents or stent segments (hereinafter referred to collectively as stent segments) to interconnect them with a somewhat constrained freedom of motion relative to each other, i.e., not loosely connected but flexibly connected. The stent segments are preferably of closed cell design and even more preferably of the self-expanding type. More precisely, the interconnecting elements are of a material different than the stent material and are plastically deformable.

BRIEF DESCRIPTION OF THE DRAWING(S)

Figure 1 is a schematic showing of a stent according to the invention;

Figure 2 is a schematic showing of a closed cell stent;

Figure 3 shows the stent of Figure 2 expanded in a fragmentary view;

Figure 4 is a schematic showing of an open cell stent;

Figure 5 shows the stent of Figure 4 expanded, and

Figure 6 is a showing of a preferred connection arrangement for a stent of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figure 1, a schematic drawing of a flexible segmented stent 10 according to the invention is shown. It is preferably comprised of a plurality of closed cell stents or stent segments 12 interconnected by plastic connectors 14.

Stents 12 are most preferably of closed cell construction and of the self-expandable type such as NITINOL stents which are cut or etched from tubular stock or rolled from cut or etched flat sheet or other shape memory metals which do not themselves exhibit permanent deformation.

Generally speaking, a self-expanding stent tends to return to its unconstrained or expanded condition. Also, in this type of stent it is generally preferred that it be of a closed cell construction. In accordance with this invention it has been found to be particularly advantageous to use self-expanding elastic material for the stent or stent segment, i.e., a material which is not "plastic" or "deformable" and to use a "plastic" "deformable" material for the connector elements. Such materials as plastic, i.e., polymeric, which may be biodegradable, metals such as gold, or viscoelastic polymers such as polyethylene may be used. Such connectors provide constrained motion yet some flexibility of the stent portions relative to each other and allow for permanent expansion of the combination as needed.

Alternatively, the stents may be of the type which are expandable with an outward radial pressure as is known in the art and may be of closed cell or open cell construction. Such stents may be of metal such as stainless steel, titanium, nickel or any other metal compatible with the body. However, in this type of combination, the connector elements will, according to the invention, be of a different material than the stents or stent segments yet the connector elements will be of a "plastic", i.e., deformable material such as a polymer or the like as pointed out above.

In use, these stent combinations will allow for the provisions of relatively long stents which may be trimmed to any desired length at the time of the procedure.

Figure 2 is a specific example of one type of closed cell construction in a stent 14. Figure 3 shows the closed cells of stent 14 when expanded.

Figure 4 is an example of open cell construction in a stent 16. Figure 5 shows the open cells of stent 16 when expanded.

In one embodiment of the invention, it relates to self expanding stents or stent segments interconnected by connector elements of a different material exhibiting permanent deformation, i.e., "plastic behavior" upon expansion, the stents preferably being of closed cell construction.

In another embodiment of the invention it relates to balloon expandable or the like stents or stent segments rigidly interconnected by structural connector elements of a different "plastic" material than the stents or stent segments, preferably polymeric plastic, most preferably biodegradable, although in the case of a metal stent, the connector may be of a different metal exhibiting different permanent deformation characteristics, i.e., plastic behavior.

Connector elements may be of any of the variety of implantable grade metals or polymeric plastics such as polytetrafluoroethylene, polyethylene, polypropylene, nylon, polyester, polyurethane and others exhibiting permanent deformation and of a material different from that of the stent or stent segment *per se*.

The connector elements may also be of biodegradable material such as polycaprolactone, polyglycolic acid, polylactic acid and the like, so long as the material exhibits permanent deformation and form a structural part of the stent combination.

If the stents are of metal they may be coated with a biocompatible material such as polyurethane, polyethylene, polytetrafluorethylene, silicone, block copolymers of polyurethane, polyethylene and silicone, biodegradable polymers such as polylactic acid, polyglycollic acid and/or hydroxy butyrate or valerate copolymer.

In such an instance, the connectors may be fused to the coating on each stent segment to interconnect them.

Most preferably however, interconnection between stents is accomplished as shown in Figure 6. In such an arrangement, a raised portion 18 is formed on connector 20 and an opening 22 is formed in stent 24, the opening 22 being shaped to receive portion 18 and interfit therewith. Of course, the reverse arrangement may be used in which the received portion 18 is on stent 22 and the opening 22 is on the connector 20.

The connectors are preferably flat and elongated but may be of various configurations such as straight, S-shaped, U-shaped, etc., and of different cross-section.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

This application claims priority from US Application No.09/346826 incorporated herein by reference.

WHAT IS CLAIMED IS:

1. A segmented stent combination comprising a plurality of aligned, generally annular and radially self-expanding stent segments, adjacent segments being interconnected to adjacent segments by at least one interconnector element of a plasticly deformable material to provide flexible yet constrained relative motions between the stent segments.

2. The segmented stent of claim 1 wherein the stent segments are of closed cell construction.

3. The segmented stent of claim 1 wherein the stent segments are of metal.

4. The segmented stent of claim 3 wherein the stent segments are of a shape memory material.

5. The segmented stent of claim 4 wherein the shape memory material is a metal.

6. The segmented stent of claim 3 wherein the stent segments are coated with a polymeric material and the interconnecting lengths of plastic material are fused to the polymer coating.

7. The segmented stents of claim 3 wherein the polymeric coating and the lengths of polymeric material are of the different composition.

8. The segmented stent of claim 3 wherein the stent segments include at least one anchor point means for receiving a length of polymeric material and the length of material includes interfitting means for connection to the anchor point means.

9. The segmented stent of claim 8 wherein the anchor point means forms a raised portion and the interfitting means on the length of polymeric material comprises an opening sized to fit over the anchor point means and interlock therewith.

10. The segmented stent of claim 8 wherein the length of polymeric material includes at each end a raised portion and the stent segments each include at least one opening sized to receive a raised portion and interlock therewith.

11. The segmented stent of claim 1 wherein each stent segment is designed and arranged as an independent stent body capable of individual support in a body vessel.

12. The segmented stent of claim 1 wherein the interconnector elements are biodegradable.

13. A segmented stent combination comprising a plurality of aligned, generally annular and radially expandable stent segments, adjacent segments being interconnected to adjacent segments by at least one interconnector element of a plasticly deformable material to provide flexible yet constrained relative motions between the stent segments, wherein the stent segments are of metal and the interconnector elements are of a different metal, exhibiting different permanent deformation characteristics than the stent segments. .

14. The segmented stent of claim 13 wherein the stent segments are of balloon expandable construction.

15. A segmented stent combination comprising a plurality of aligned, generally annular and radially expandable stent segments, adjacent segments being interconnected to adjacent segments by at least one interconnector element of a viscoelasticly deformable material to provide flexible yet constrained relative motions between the stent segments.

16. The segmented stent of claim 15 wherein the stent segments are of the self-expanding type.

17. The segmented stent of claim 15 wherein the stent segments are of closed cell construction.

18. The segmented stent of claim 15 wherein the stent segments are of metal.

19. The segmented stent of claim 18 wherein the stent segments are of a shape memory material.

20. The segmented stent of claim 19 wherein the shape memory material is a metal.

21. The segmented stent of claim 18 wherein the stent segments are coated with a polymeric material and the interconnecting lengths of plastic material are fused to the polymer coating.

22. The segmented stents of claim 18 wherein the polymeric coating and the lengths of polymeric material are of the different composition.

23. The segmented stent of claim 15 wherein the stent segments are of balloon expandable construction and are of metal and the interconnector elements are of a different metal, exhibiting different permanent deformation characteristics than the stent segments.

24. The segmented stent of claim 18 wherein the stent segments include at least one anchor point means for receiving a length of polymeric material and the length of material includes interfitting means for connection to the anchor point means.

25. The segmented stent of claim 24 wherein the anchor point means forms a raised portion and the interfitting means on the length of polymeric material comprises an opening sized to fit over the anchor point means and interlock therewith.

26. The segmented stent of claim 24 wherein the length of polymeric material includes at each end a raised portion and the stent segments each include at least one opening sized to receive a raised portion and interlock therewith.

27. The segmented stent of claim 15 wherein each stent segment is designed and arranged as an independent stent body capable of individual support in a body vessel.

28. The segmented stent of claim 15 wherein the interconnector elements are biodegradable.

29. The segmented stent of claim 15 wherein the stent segments are of closed cell construction and are self-expandable.

30. A segmented stent combination comprising a plurality of aligned, generally annular and radially expandable stent segments, adjacent segments being interconnected to adjacent segments by at least one interconnector element of a plasticly deformable material to provide flexible yet constrained relative motions between the stent segments, wherein the stent segments include at least one anchor point means for receiving a length of polymeric material and the length of material includes interfitting means for connection to the anchor point means.

31. The segmented stent of claim 30 wherein the anchor point means forms a raised portion and the interfitting means on the length of polymeric material comprises an opening sized to fit over the anchor point means and interlock therewith.

32. The segmented stent of claim 30 wherein the length of polymeric material includes at each end a raised portion and the stent segments each include at least one opening sized to receive a raised portion and interlock therewith.

Fig. 1

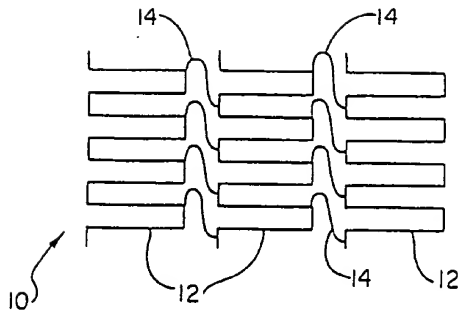


Fig. 2

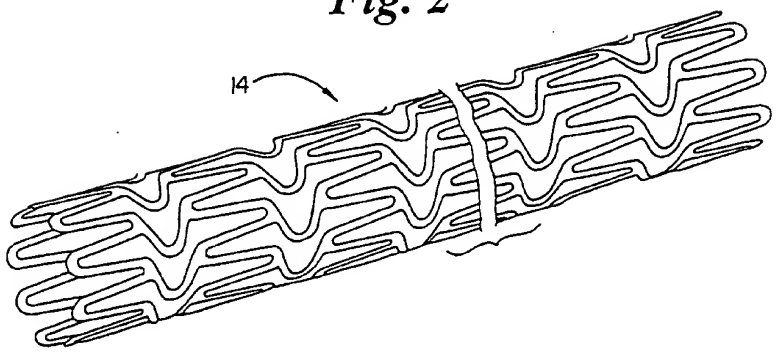
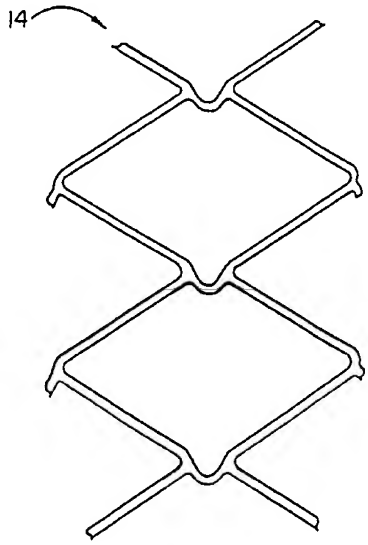


Fig. 3



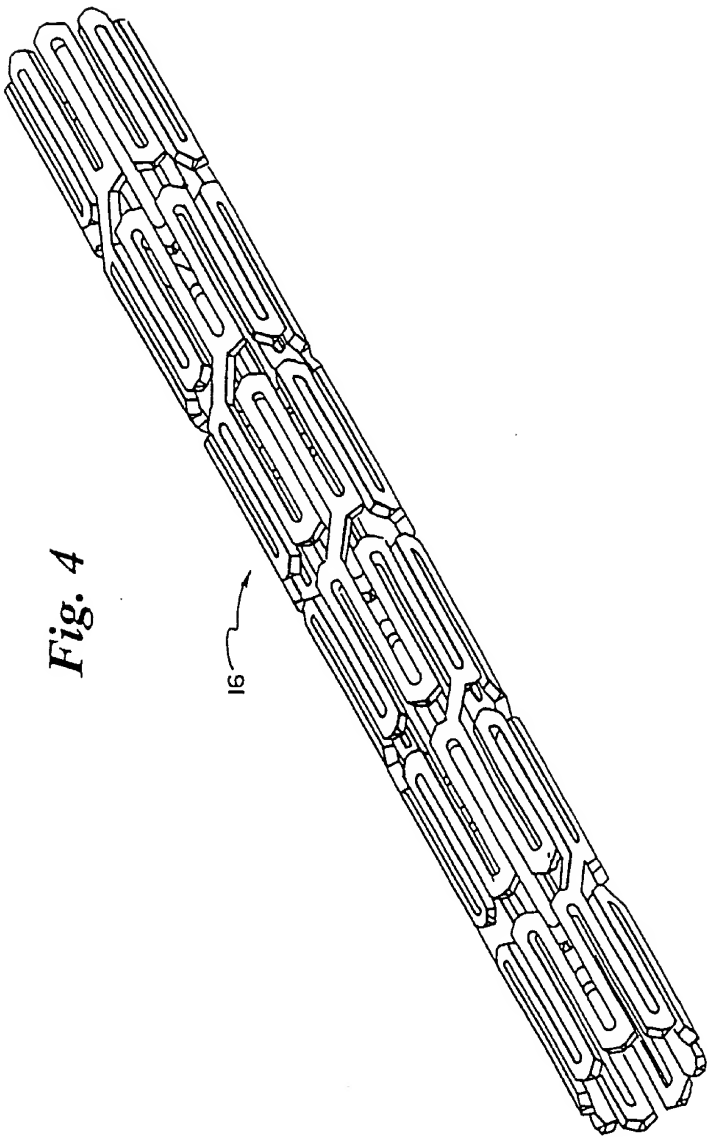


Fig. 4

Fig. 5

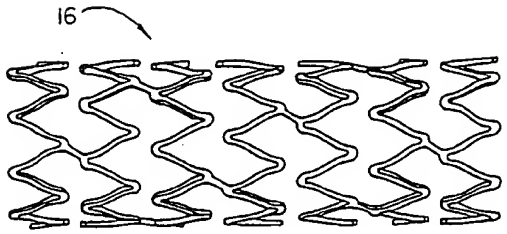
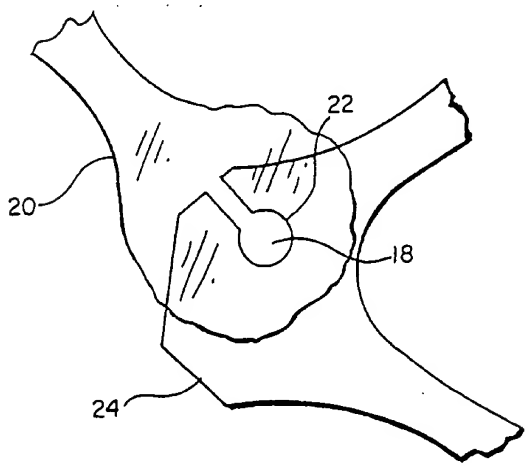


Fig. 6



INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/US 00/17986

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 31945 A (SCIMED LIFE SYSTEMS, INC.) 30 November 1995 (1995-11-30) page 9, line 22 - line 29; figures 5A,5B	13,14
A	US 5 843 175 A (FRANTZEN) 1 December 1998 (1998-12-01) column 14, line 56 -column 15, line 2; figures 22,23	1,13,15
A	EP 0 541 443 A (MEADOX FRANCE) 12 May 1993 (1993-05-12) abstract; figures	15
A	WO 98 20810 A (MEDTRONIC, INC.) 22 May 1998 (1998-05-22) page 23, line 9 - line 35; figures 9,10	30

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
3 October 2000	10/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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